

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
Sheet		1	of	1	Application Number: 10/792,376 Filing Date: 03/04/2004 First Named Inventor: Vladimir SABETSKY Group Art Unit: Unassigned 1654 Examiner Name: Unassigned Hemant Attorney Docket Number: 028093-0113

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
HK	B1	4,963,526	A	ECANOW	10-16-1990	
HK	B2	5,849,884	A	WOISZWILLO, BROWN et al.	12-15-1998	
HK	B9	2004/0048782	A1	BRYSON	3-11-04	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
HK	B3	EP	1 371 364	A	OCTOPLUS B.V.	12-17-2003		
HK	B4	WO	87/02704	A	ROBINSON	05-07-1987		
HK	B5	WO	99/02107	A	US BIOMATERIALS CORPORATION	01-21-1999		
HK	B6	WO	02/28374	A1	FLAMEL TECH SA	04-11-2002		
HK	B7	WO	02/39985	A	BIOGLAN AB	05-23-2002		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
HK	B8	SOON-SHIONG, "Encapsulated islet cell therapy for the treatment of diabetes: Intraperitoneal injection of islets," <u>Journal of Controlled Release</u> , May 1, 1996, pp. 399-407, Vol. 39, No. 2, Elsevier Science Publishers B.V., Amsterdam, NL	

Examiner Signature	/Hemant Khanna/	Date Considered	11/20/2006
--------------------	-----------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Date Submitted: 4/21/04

(use as many sheets as necessary)

Complete if Known

Application Number	10/792,376
Filing Date	3/4/04
First Named Inventor	Vladimir SABETSKY
Group Art Unit	Unassigned 1654
Examiner Name	Unassigned Hemant Khanna
Attorney Docket Number	028093-0113

Sheet

1

of

3

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
HK	A1	2002/0054914		Morcol, Tulin et al	5/9/02	
HK	A2	6,482,413	B1	Chalasani, et al	11/19/02	
HK	A3	6,395,302	B1	Hennink et al	5/28/02	
HK	A4	6,303,148	B1	Hennink et al	10/16/01	
HK	A5	4,713,249		Schroder	12/15/87	
HK	A6	6,264,943	B1	Cherksey	7/24/01	
HK	A7	Re 37,950	E	Dunn et al	12/31/02	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
HK	A8	EP	1 184 032	A1	OctoPlus B.V.	3/6/02		Y
HK	A9	WO	02/17884	A1	Octoplus B.V.	3/7/02		Y
HK	A10	WO	03/024425	A1	McGurk	3/27/03		Y
HK	A11	WO	98/14174		Vivorx Pharm Inc	4/9/98		Y
HK	A12	WO	01/01964	A2	Sedum Laboratories Inc.	1/11/01		Y
HK	A13	WO	84/00294		Schroder, Ulf	2/2/84		Y

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
HK	A14	Griffith L. Acta Mater. 48 (2000): 263-277	Y
HK	A15	Angelova N. and Hunkeler D., TIBTECH, 17 (1999): 409-421	Y
HK	A16	Tirrell M., Kokkoli E., Biesalski M., Surface Science 500 (2002): 61-83	Y
HK	A17	Madsen S., Moony D., PSTT 11 (2000): 381-384	Y

Examiner Signature

/Hemant Khanna/

Date Considered

11/20/2006

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	10/792,376
				Filing Date	3/4/04
				First Named Inventor	Vladimir SABETSKY
				Group Art Unit	Unassigned 1654
				Examiner Name	Unassigned Hemant Khanna
Date Submitted: 4/21/04				Attorney Docket Number	028093-0113
(use as many sheets as necessary)					
Sheet	2	of	3		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
HK	A18	Eliaz R., Szoka F., Gene Therapy 9 (2002): 1230-1237	Y
HK	A19	Blain J.F., Maghni K., Pelletier S. and Sirois P. Inflamm. Res. 48 (1999): 386-392	Y
HK	A20	Crystallized carbohydrate spheres as a slow release matrix for biologically active substances, Ulf Schroder, Biomaterials 1984, Vol. 5 March	Y
HK	A21	Crystallized Carbohydrate Spheres for Slow Release and Targeting, Ulf Schroder, Methods in Enzymology, Vol. 12	Y
HK	A22	Surfactant-Free Preparation of Biodegradable Hydrogel Microspheres for Protein Release, Yasuhiko Tabata, et al., Journal of Bioactive and Compatible Polymers, Vol. 14-September 1999	Y
HK	A23	Partitioning in Aqueous Two-Phase Systems. A comprehensive bibliography in three parts: (1956-1984; 1985-1990; 1991-present) Part III: 1991-present Part II: 1985-1990	Y
HK	A24	Local and distant transfection of mdx muscle fibers with dystrophin and LacZ genes delivered in vivo by synthetic microspheres, A. Baranov, et al., Gene Therapy 6 (1999), 1406-1414	Y
HK	A25	Regulated insulin release from biodegradable dextran hydrogels containing poly(ethylene glycol), Kazuteru Moriyama, et al., Journal of Controlled Release 42 (1996) 237-248	Y
HK	A26	Lantus Prescribing Information – Aventis Pharmaceuticals ( <a href="http://www.aventis-us.com/PIs/lantus_TXT.html">http://www.aventis-us.com/PIs/lantus_TXT.html</a> visited 2/23/04	Y
HK	A27	Sephadex-based cell-affinity adsorbents: preparation and performance, Geert Besselink, et al, Biotechnol., Appl. Biochem. 35 (2002), 55-60	Y
HK	A28	Formation of dextran hydrogels by crystallization, R.J.H. Stenekes, et al., Biomaterials 22 (2001) 1891-0898	Y
HK	A29	Enhanced Loading and Activity Retention of Proteins in Hydrogel Delivery Systems, S.H. Gehrke, et al, Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 22 (1995), Controlled Release Society, Inc., p. 145-146	Y
HK	A30	Amidon GL, Lee HJ, Absorption of Peptide and Peptidomimetic Drugs, Ann. Rev. Pharmacol. Toxicol 1994; 34: 321-41	Y
HK	A31	Abstract, Pharmacological Management of Type 2 Diabetes Mellitus: rationale for rational use of insulin., Mayo Clin Proc. 2003 Apr; 78(4): 459-67, Chan JL, Abrahamson MJ, Mayo Clin Proc. 2003 Apr;78(4):411-3	A

Examiner Signature	/Hemant Khanna/	Date Considered	11/20/2006
--------------------	-----------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  Date Submitted: 4/21/04 (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/792,376
				Filing Date	3/4/04
				First Named Inventor	Vladimir SABETSKY
				Group Art Unit	Unassigned 1654
				Examiner Name	Unassigned Hemant Khanna
				Attorney Docket Number	028093-0113
Sheet	3	of	3		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>6</sup>
HK	A32	Abstract, Improvement of Transmucosal Absorption of Biologically Active Peptide Drugs, Akira Yamamoto, Department of Biopharmaceuticals, Kyoto Pharmaceutical University, Misasagi 8/31/2001		A
HK	A33	Abstract, 2002 American Diabetes Association Annual Meeting, Significant Hypoglycemic Effect of a Perorally-delivered Insulin in the Treatment of Streptozocin-induced Diabetic Rats, Frank K. Leung, Jiang Li, Lanqui Huang and Emily Leung.		A
HK	A34	Abstract, Oligopeptides as Potential Insulin Drug Delivery System, Raphael M. Ottenbrite, Rui Zhao, Mamoru Haratake, Dept. of Chemistry, Virginia Commonwealth University, Richmond, VA		A
HK	A35	Abstract, Insulin loaded multilayer dextran sulfate/protamine microparticles Nadezda G. Balabushevich <sup>1</sup> , Gleb B. Sukhorukov <sup>2</sup> and Natalia I. Larionova, 1 Department of Chemistry, Moscow State University, 119992 Russia, 2 Max-Planck Institute of Colloids and Interfaces, Golm/Potsdam, 14424, German.		A
HK	A36	Abstract, Insulin Containing Polyethyleneimine-dextran Sulfate Nanoparticles, Int J. Pharm. 2003 Apr 14; 255(1-2):139-51, Tiyaaboonchai W., Woiszwilllo J., Sims RC, Middaugh CR, Dept. of Pharmaceutical Chemistry, School of Pharmacy, The University of Kansas, 2095 Constant Ave., Lawrence, KS 66047-3729 USA		A
HK	A37	Abstract, Microfabricated porous silicon particles enhance paracellular delivery of insulin across intestinal Caco-2 cell monolayers, Pharm Res. 2003 Jan; 20(1):110-6., Forasker AB, Walczak RJ, Cohen MH, Boiarski TA, Grove CF, Swaan PW, The Ohio State University of Pharmacy, Division of Pharmaceutics, 500 West 12 <sup>th</sup> Ave., Columbus, OH 43210, USA		A
HK	A38	Abstract, Gastrointestinal absorption enhancement of Insulin by administration of enteric microspheres and SNAC to rats, J. Microencapsul. 2004 Jan-Feb; 21(1): 37-45, Qi R, Ping QN		A
HK	A39	Abstract, Preparation and characterization of enteric microspheres containing bovine insulin by a w/o/w emulsion solvent evaporation method, Chem Pharm Bull (Tokyo) 1998 Oct; 46(10): 1613-7, Nagareya N., Uchida T, Matsuyama K.		A
HK	A40	Abstract, Intestinal absorption of human insulin in pigs using delivery systems based on superporous hydrogel polymers, Int J. Pharm. 2002 Oct 24; 247(1-2): 57-66, Dorkoosh FA, Verhoef JC, Borchard G, Rafiee-Tehrani M, Verheijden JH, Junginger HE		A
HK	A41	Abstract, Peroral delivery systems based on superporous hydrogel polymers: release characteristics for the peptide drugs buserelin, octreotide and insulin, Eur J Pharma Sci. 2002 Jun; 15(5): 433-9, Dorkoosh FA, Coos Verhoef J, Ambagts MH, Rafiee-Tehrani M, Borchard G, Junginger HE		A
HK	A42	Abstract, Development and characterization of a novel peroral peptide drug delivery system. J Control Release. 2001 Apr 28; 71(3): 307-18, Dorkoosh FA, Verhoef JC, Borchard G, Rafiee-Tehrani M, Junginger HE		A

Examiner Signature	/Hemant Khanna/	Date Considered	11/20/2006
--------------------	-----------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.